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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,027	08/28/2003	Laurent Schaller	CSI-2008C2	1555

7590 07/11/2008

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EXAMINER	
WOO, JULIAN W	
ART UNIT	PAPER NUMBER
3773	
MAIL DATE	DELIVERY MODE
07/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/653,027	SCHALLER ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/28/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1 and 3-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 9-69 of copending Application No. 10/208,405. The conflicting claims are not identical; they are not patentably distinct from each other because they contain substantially the same subject matter: a tissue connector/clip, needles, release mechanism, and flexible members comprising substantially the same elements and configurations.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 11, 12, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sander (5,374,268). Sander discloses, at least in figure 1 and in col. 3, line 35 to col. 4, line 3; ; a tissue connector assembly, where the assembly includes first and second tissue piercing members (12), a surgical fastener (16 and one 14 combined) adapted to assume a loop configuration and having first and second end portions, the first tissue piercing member being coupled to the first end portion and the second tissue piercing member being coupled to the second end portion (via 14); a flexible member (14--made of a flexible polymer) with a first end portion coupled to the first tissue piercing member and a second portion having coupled to the first end portion of the fastener, where the assembly includes a coupling ("heat-shrinkable tubing") coupling the first tissue piercing member and the first end portion of the fastener (via 14), where the coupling comprises a tubular member (e.g., "heat-shrinkable tubing" at 20), where the tubular member has movable portions and the surgical fastener (at 14) includes an enlarged portion (at 18) adapted to receive the movable portions; where the assembly includes a second coupling ("heat shrinkable tubing") coupled to the second fastener end portion and the second piercing member (via another element 14).

5. Claims 1, 28, 29, and 31-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Bolduc et al. (6,254,615). Bolduc et al. disclose, at least in figures 12F and 12G and in col. 16, line 62 to col. 17, line 14; a tissue connector assembly including a surgical fastener (224 with respect to claims 1, 28, and 29, or 222 with respect to claims 31-35) adapted to assume a loop configuration and having first and second end portions, a first tissue or discrete tissue piercing member (point of 220) coupled to the first end portion and a second tissue or discrete tissue piercing member (another point of 220) coupled to the second end portion, and a flexible member (222) having a first end portion coupled to the first piercing member and a second end portion couple to the first end portion of the fastener, where the first and second tissue piercing members comprise needles, where the surgical fastener comprises a clip or a wire comprising shape memory material (Nitinol), where the clip has an open configuration (see fig. 12F) and a closed configuration (see fig. 12G), where the clip is in the closed configuraiton when in a relaxed state (in a patient's body), and where the clip is generally U-shaped in the open configuration and assumes a spiral configuration in the closed confiruation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 3-5, 7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup (5,972,024) in view of Krajicek (5,413,597). Northrup discloses the invention substantially as claimed. Northrup discloses, at least in figures 4-9 and col. 4, lines 5-54; a tissue connector assembly, where the assembly includes first and second tissue piercing members (40), a surgical fastener (e.g., 310 in fig. 9) adapted to assume a loop configuration and having first and second end portions (i.e., one end of the fastener has two portions for receiving the piercing members and flexible members), the first tissue piercing member being coupled to the first end portion and the second tissue piercing member being coupled to the second end portion; a flexible member (20) with a first end portion coupled to the first tissue piercing member and a second portion having coupled to the first end portion of the fastener; a second flexible member (another 20) the second flexible member having a first end portion coupled to the second tissue piercing member and a second end portion couple to the second end portion; where the flexbible members comprise suture, where tissue piercing members comprise needles. However, Northrup does not disclose that the surgical fastener is an apparatus or an artificial element. Krajicek teaches, at least in figure 1 and in col. 1, line

62 to col. 2, line 14; a surgical fastener usable for the anastomosis as disclosed by Northrup. It would have been obvious to one having ordinary skill in the art to apply an artificial surgical fastener, in view of Krajicek, in the apparatus of Northrup. Such a fastener would be useful for replacing or repairing a defective vascular structure, and it would effectively prevent leakage around the clips when the connector and clips are joined to another vascular structure.

8. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup (5,972,024) in view of Krajicek (5,413,597), and further in view of Pyka et al. (5,002,563). Northrup in view of Krajicek discloses the invention substantially as claimed. However, Northrup in view of Krajicek does not disclose that the flexible member comprises metal. Pyka et al. teach, at least in figures 5A-6B2 and col. 4, lines 26-58; a flexible member comprising metal. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply a flexible member as taught by Pyka et al. in the device of Northrup in view of Krajicek. Such a flexible member would help draw tissue parts together and hold the tissue parts firmly together.

Response to Amendment

9. Applicant's arguments with respect to claims 1 and 3-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

July 10, 2008